

upon implementation of such controls, the event is unlikely or its consequences are less than those in paragraphs (c)(1)–(4) of this section. Intermediate consequence events are those internally or externally initiated events that are not high consequence events, that result in:

(1) An acute worker dose of 0.25 Sv (25 rem) or greater total effective dose equivalent;

(2) An acute dose of 0.05 Sv (5 rem) or greater total effective dose equivalent to any individual located outside the controlled area identified pursuant to paragraph (f) of this section;

(3) A 24-hour averaged release of radioactive material outside the restricted area in concentrations exceeding 5000 times the values in Table 2 of Appendix B to Part 20; or

(4) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that:

(i) Could lead to irreversible or other serious, long-lasting health effects to a worker, or

(ii) Could cause mild transient health effects to any individual located outside the controlled area as specified in paragraph (f) of this section. If an applicant possesses or plans to possess quantities of material capable of such chemical exposures, then the applicant shall propose appropriate quantitative standards for these health effects, as part of the information submitted pursuant to § 70.65 of this subpart.

(d) In addition to complying with paragraphs (b) and (c) of this section, the risk of nuclear criticality accidents must be limited by assuring that under normal and credible abnormal conditions, all nuclear processes are subcritical, including use of an approved margin of subcriticality for safety. Preventive controls and measures must be the primary means of protection against nuclear criticality accidents.

(e) Each engineered or administrative control or control system necessary to comply with paragraphs (b), (c), or (d) of this section shall be designated as an item relied on for safety. The safety program, established and maintained pursuant to § 70.62 of this subpart, shall ensure that each item relied on for safety will be available and

reliable to perform its intended function when needed and in the context of the performance requirements of this section.

(f) Each licensee must establish a controlled area, as defined in § 20.1003. In addition, the licensee must retain the authority to exclude or remove personnel and property from the area. For the purpose of complying with the performance requirements of this section, individuals who are not workers, as defined in § 70.4, may be permitted to perform ongoing activities (e.g., at a facility not related to the licensed activities) in the controlled area, if the licensee:

(1) Demonstrates and documents, in the integrated safety analysis, that the risk for those individuals at the location of their activities does not exceed the performance requirements of paragraphs (b)(2), (b)(3), (b)(4)(ii), (c)(2), and (c)(4)(ii) of this section; or

(2) Provides training that satisfies 10 CFR 19.12(a)(1)–(5) to these individuals and ensures that they are aware of the risks associated with accidents involving the licensed activities as determined by the integrated safety analysis, and conspicuously posts and maintains notices stating where the information in 10 CFR 19.11(a) may be examined by these individuals. Under these conditions, the performance requirements for workers specified in paragraphs (b) and (c) of this section may be applied to these individuals.

§ 70.62 Safety program and integrated safety analysis.

(a) *Safety program.* (1) Each licensee or applicant shall establish and maintain a safety program that demonstrates compliance with the performance requirements of § 70.61. The safety program may be graded such that management measures applied are graded commensurate with the reduction of the risk attributable to that item. Three elements of this safety program; namely, process safety information, integrated safety analysis, and management measures, are described in paragraphs (b) through (d) of this section.

(2) Each licensee or applicant shall establish and maintain records that

demonstrate compliance with the requirements of paragraphs (b) through (d) of this section.

(3) Each licensee or applicant shall maintain records of failures readily retrievable and available for NRC inspection, documenting each discovery that an item relied on for safety or management measure has failed to perform its function upon demand or has degraded such that the performance requirements of § 70.61 are not satisfied. These records must identify the item relied on for safety or management measure that has failed and the safety function affected, the date of discovery, date (or estimated date) of the failure, duration (or estimated duration) of the time that the item was unable to perform its function, any other affected items relied on for safety or management measures and their safety function, affected processes, cause of the failure, whether the failure was in the context of the performance requirements or upon demand or both, and any corrective or compensatory action that was taken. A failure must be recorded at the time of discovery and the record of that failure updated promptly upon the conclusion of each failure investigation of an item relied on for safety or management measure.

(b) *Process safety information.* Each licensee or applicant shall maintain process safety information to enable the performance and maintenance of an integrated safety analysis. This process safety information must include information pertaining to the hazards of the materials used or produced in the process, information pertaining to the technology of the process, and information pertaining to the equipment in the process.

(c) *Integrated safety analysis.* (1) Each licensee or applicant shall conduct and maintain an integrated safety analysis, that is of appropriate detail for the complexity of the process, that identifies:

(i) Radiological hazards related to possessing or processing licensed material at its facility;

(ii) Chemical hazards of licensed material and hazardous chemicals produced from licensed material;

(iii) Facility hazards that could affect the safety of licensed materials

and thus present an increased radiological risk;

(iv) Potential accident sequences caused by process deviations or other events internal to the facility and credible external events, including natural phenomena;

(v) The consequence and the likelihood of occurrence of each potential accident sequence identified pursuant to paragraph (c)(1)(iv) of this section, and the methods used to determine the consequences and likelihoods; and

(vi) Each item relied on for safety identified pursuant to § 70.61(e) of this subpart, the characteristics of its preventive, mitigative, or other safety function, and the assumptions and conditions under which the item is relied upon to support compliance with the performance requirements of § 70.61.

(2) Integrated safety analysis team qualifications. To assure the adequacy of the integrated safety analysis, the analysis must be performed by a team with expertise in engineering and process operations. The team shall include at least one person who has experience and knowledge specific to each process being evaluated, and persons who have experience in nuclear criticality safety, radiation safety, fire safety, and chemical process safety. One member of the team must be knowledgeable in the specific integrated safety analysis methodology being used.

(3) Requirements for existing licensees. Individuals holding an NRC license on September 18, 2000 shall, with regard to existing licensed activities:

(i) By April 18, 2001, submit for NRC approval, a plan that describes the integrated safety analysis approach that will be used, the processes that will be analyzed, and the schedule for completing the analysis of each process.

(ii) By October 18, 2004, or in accordance with the approved plan submitted under § 70.62(c)(3)(i), complete an integrated safety analysis, correct all unacceptable performance deficiencies, and submit, for NRC approval, an integrated safety analysis summary, including a description of the management measures, in accordance with § 70.65. The Commission may approve a request for an alternative schedule for completing the correction of unacceptable performance deficiencies if the

Commission determines that the alternative is warranted by consideration of the following:

(A) Adequate compensatory measures have been established;

(B) Whether it is technically feasible to complete the correction of the unacceptable performance deficiency within the allotted 4-year period;

(C) Other site-specific factors which the Commission may consider appropriate on a case-by-case basis and that are beyond the control of the licensee.

(iii) Pending the correction of unacceptable performance deficiencies identified during the conduct of the integrated safety analysis, the licensee shall implement appropriate compensatory measures to ensure adequate protection.

(d) *Management measures.* Each applicant or licensee shall establish management measures to ensure compliance with the performance requirements of § 70.61. The measures applied to a particular engineered or administrative control or control system may be graded commensurate with the reduction of the risk attributable to that control or control system. The management measures shall ensure that engineered and administrative controls and control systems that are identified as items relied on for safety pursuant to § 70.61(e) of this subpart are designed, implemented, and maintained, as necessary, to ensure they are available and reliable to perform their function when needed, to comply with the performance requirements of § 70.61 of this subpart.

§ 70.64 Requirements for new facilities or new processes at existing facilities.

(a) *Baseline design criteria.* Each prospective applicant or licensee shall address the following baseline design criteria in the design of new facilities. Each existing licensee shall address the following baseline design criteria in the design of new processes at existing facilities that require a license amendment under § 70.72. The baseline design criteria must be applied to the design of new facilities and new processes, but do not require retrofits to existing facilities or existing processes (e.g., those housing or adjacent to the new

process); however, all facilities and processes must comply with the performance requirements in § 70.61. Licensees shall maintain the application of these criteria unless the analysis performed pursuant to § 70.62(c) demonstrates that a given item is not relied on for safety or does not require adherence to the specified criteria.

(1) *Quality standards and records.* The design must be developed and implemented in accordance with management measures, to provide adequate assurance that items relied on for safety will be available and reliable to perform their function when needed. Appropriate records of these items must be maintained by or under the control of the licensee throughout the life of the facility.

(2) *Natural phenomena hazards.* The design must provide for adequate protection against natural phenomena with consideration of the most severe documented historical events for the site.

(3) *Fire protection.* The design must provide for adequate protection against fires and explosions.

(4) *Environmental and dynamic effects.* The design must provide for adequate protection from environmental conditions and dynamic effects associated with normal operations, maintenance, testing, and postulated accidents that could lead to loss of safety functions.

(5) *Chemical protection.* The design must provide for adequate protection against chemical risks produced from licensed material, facility conditions which affect the safety of licensed material, and hazardous chemicals produced from licensed material.

(6) *Emergency capability.* The design must provide for emergency capability to maintain control of:

(i) Licensed material and hazardous chemicals produced from licensed material;

(ii) Evacuation of on-site personnel; and

(iii) Onsite emergency facilities and services that facilitate the use of available offsite services.

(7) *Utility services.* The design must provide for continued operation of essential utility services.